IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS AG, NOVARTIS PHARMACEUTICALS CORPORATION, MITSUBISHI TANABE PHARMA CORPORATION, and MITSUI SUGAR CO., LTD. Plaintiffs, v. EZRA VENTURES, LLC Defendant.	C.A. No. 1:15-cv-00150-LPS

EZRA VENTURES, LLC'S ANSWER,
AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

This Answer, Affirmative Defenses, and Counterclaims filed by Ezra Ventures, LLC ("Ezra"), involves U.S. Patent No. 5,604,229. Ezra, by and through its counsel, answer Plaintiffs' Complaint as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code. This action relates to Abbreviated New Drug Application ("ANDA") No. 20-7945 filed by Ezra Ventures, LLC with the U.S. Food and Drug Administration ("FDA") for approval to engage in the commercial manufacture, use or sale of fingolimod capsules 0.5 mg, a generic version of Novartis's GILENYA® Capsules, 0.5 mg, prior to expiration of U.S. Patent No. 5,604,229 ("the '229 patent").

Answer: Paragraph 1 contains conclusions of law for which no response is required. To the extent one is required, Ezra admits that a civil action regarding the ’229 patent has been filed against it by the Plaintiffs and that Ezra has filed ANDA No. 20-7945 with the FDA. All other allegations are denied.

RELATED ACTION

2. Plaintiffs have filed another patent infringement action currently pending before this Court involving the ’229 patent, captioned *Novartis AG, et al. v. Actavis Inc. et al.*, C.A. No. 1:14-cv-01487-LPS (D. Del.).

Answer: Ezra admits there is another patent infringement action currently pending before this Court, captioned *Novartis AG, et al. v. Actavis Inc. et al.*, C.A. No. 1:14-cv-01487-LPS (D. Del.). The Complaint speaks for itself in that action. All other allegations are denied.

PARTIES

3. Novartis AG is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

Answer: On information and belief, Ezra admits to Novartis AG’s address as stated but is without knowledge or information to determine the truth of the remaining allegations and accordingly Ezra denies them.

4. Novartis Pharmaceuticals Corporation (“NPC”) is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in East Hanover, New Jersey.

Answer: On information and belief, Ezra admits to NPC's address as stated but is without knowledge or information to determine the truth of the remaining allegations and accordingly Ezra denies them.

5. Mitsubishi Tanabe Pharma Corporation ("MTPC") is a corporation organized and existing under the laws of Japan, having an office and place of business at 2-6-18, Kitahama, Chuo-ku, Osaka 541-8505, Japan.

Answer: On information and belief, Ezra admits to MTPC's address as stated but is without knowledge or information to determine the truth of the remaining allegations and accordingly Ezra denies them.

6. Mitsui Sugar Co., Ltd. ("Mitsui") is a corporation organized and existing under the laws of Japan, having an office and place of business at 36-2, Nihonbashi Hakozakicho, Chuo-ku 103-8423, Tokyo, Japan.

Answer: On information and belief, Ezra admits to Mitsui's address as stated but is without knowledge or information to determine the truth of the remaining allegations and accordingly Ezra denies them.

7. Upon information and belief, Ezra Ventures, LLC ("Ezra") is a corporation organized and existing under the laws of the State of Arkansas, having its principal place of business at 401 S. Cedar Street, Little Rock, Arkansas, 72205.

Answer: Admitted.

8. Upon information and belief, following any FDA approval of ANDA No.20-7945, Ezra will make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 20-7945 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

Answer: Ezra admits that it has filed ANDA No. 20-7945 seeking approval to offer certain generic drug products. All other allegations are denied as the remaining allegations relate to future events.

9. NPC and Novartis AG are collectively referred to hereafter as "Novartis."

Answer: Paragraph 9 contains only an arbitrary definition of "Novartis" to which no response is required. To the extent one is required, Ezra admits that Plaintiffs have so defined "Novartis" in the Complaint.

JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.,* and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

Answer: Paragraph 10 contains conclusions of law for which no response is required. To the extent one is required, Ezra admits that a civil action regarding the '229 patent has been filed against it by the Plaintiffs but denies that venue is proper in this Court.. All other allegations are denied.

11. This Court has personal jurisdiction over Ezra because, among other things, it has committed, or aided, abetted, contributed to, or participated in the commission of, a tortious act of patent infringement in filing ANDA No. 20-7945 that has led to foreseeable harm and injury to NPC, a Delaware corporation.

Answer: Ezra denies the allegations of this paragraph.

12. This Court also has personal jurisdiction over Ezra because its activities (*e.g.*, filing ANDA No. 20-7945 and sending notice of a paragraph IV certification) were purposefully

directed to the state of Delaware, where plaintiff NPC is organized. As a result, the consequences of Ezra's actions were (and will be) suffered in Delaware.

Answer: Paragraph 12 contains conclusions of law for which no response is required. To the extent one is required, Ezra denies that this Court has any personal jurisdiction over Ezra. Ezra denies the remaining allegations of this paragraph.

13. This Court also has personal jurisdiction over Ezra because this suit arises out of and relates to Ezra's activities that are, and will be, directed to Delaware. This suit arises from Ezra's ANDA filing, which is a prerequisite to obtaining FDA approval, which in turn is necessary in order for Ezra to sell its ANDA product in Delaware.

Answer: Paragraph 13 contains conclusions of law for which no response is required. To the extent one is required, Ezra denies that this Court has any personal jurisdiction over Ezra. Ezra denies the remaining allegations of this paragraph.

14. This Court also has personal jurisdiction over Ezra because at the time Ezra sent notice of a paragraph IV certification, it was reasonably foreseeable that Ezra would be sued within 45 days in this District, where NPC is organized and where related ANDA litigation had already been filed.

Answer: Paragraph 14 contains conclusions of law for which no response is required. To the extent one is required, Ezra denies that this Court has any personal jurisdiction over Ezra. Ezra denies the remaining allegations of this paragraph.

15. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Ezra.

Answer: Paragraph 15 contains conclusions of law for which no response is required. To the extent one is required, Ezra denies that this Court has any personal jurisdiction over Ezra.

THE PATENT-IN-SUIT AND GILENYA®

16. On February 18, 1997, the U.S. Patent and Trademark Office duly and legally issued the ’229 patent, entitled “2-Amino-1,3-Propanediol Compound and Immunosuppressant.” A true and correct copy of the ’229 patent is attached hereto as **Exhibit A**. The claims of the ’229 patent are valid and enforceable. The ’229 patent is owned by Mitsui and MTPC and exclusively licensed to Novartis. Plaintiffs have the right to sue for and obtain equitable relief and damages for infringement of the ’229 patent.

Answer: Ezra admits that the issue date of the ’229 patent is February 18, 1997 and bears the title, “2-Amino-1,3-Propanediol Compound and Immunosuppressant.” Ezra lacks information or knowledge sufficient to form a belief as the truth or falsity of the remaining allegations, and accordingly denies the same. Ezra specifically denies that the ’229 patent was duly and legally issued.

17. NPC is the holder of New Drug Application (“NDA”) No. 022527 by which the FDA granted approval for the commercial manufacturing, marketing, sale, and use of GILENYA® (fingolimod) Capsules, 0.5 mg. GILENYA® is the first in a new class of compounds known as sphingosine 1-phosphate receptor (S1PR) modulators. GILENYA® is indicated to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability in patients with relapsing forms of multiple sclerosis. GILENYA® is the first oral drug that has been approved by the FDA for such an indication.

Answer: On information and belief, NPC holds approved New Drug Application (“NDA”) No. 22-527 for 0.5 mg fingolimod capsules, which are prescribed and sold in the United States under the name GILENYA®. Ezra is without knowledge or information to

determine the truth of the remaining allegations in this paragraph and accordingly Ezra denies them.

18. GILENYA® and the use of GILENYA® is covered by one or more claims of the ’229 patent.

Answer: Denied.

19. The FDA’s official publication of approved drugs (the “Orange Book”) lists the ’229 patent in connection with GILENYA®.

Answer: Admitted.

INFRINGEMENT BY EZRA OF THE PATENT-IN-SUIT

20. Plaintiffs incorporate each of the preceding paragraphs 1-19 as if fully set forth herein.

Answer: Ezra reincorporates by reference its Answers to Paragraphs 1-19.

21. By letters dated January 2, 2015 (“the Notice Letters”), Ezra notified Plaintiffs that Ezra had submitted to the FDA ANDA No. 20-7945 for fingolimod capsules 0.5mg, a drug product that is a generic version of GILENYA® (“Ezra's ANDA Product”). The purpose of Ezra’s submission of the ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act (“FDCA”) to engage in the commercial manufacture, use, offer for sale, and/or sale of Ezra’s ANDA Product prior to the expiration of the ’229 patent.

Answer: Ezra admits that it filed ANDA No. 20-7945. Ezra admits that it sent so-called Notice Letters to the Plaintiffs. The Notice Letters speak for themselves. Ezra denies the remaining allegations as such allegations relate to future events.

22. In the Notice Letters, Ezra notified Plaintiffs that, as a part of its ANDA, Ezra had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21

U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the ’229 patent asserting that the ’229 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and sale of Ezra's ANDA Product.

Answer: The Notice Letters speak for themselves. Ezra admits that its ANDA included a certification under the above mentioned statutory section. The remaining allegations are denied.

23. This Complaint is being filed before the expiration of forty-five days from the date Plaintiffs received the Notice Letters.

Answer: Admitted.

24. By filing ANDA No. 20-7945, Ezra has necessarily represented to the FDA that, upon approval, Ezra's ANDA Product will have the same active ingredient, method of administration, dosage form, and strength as GILENYA®, and will be bioequivalent to GILENYA®.

Answer: Paragraph 24 contains conclusions of law for which no response is required. To the extent one is required, Ezra denies the allegations.

25. Ezra’s submission of ANDA No. 20-7945 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Ezra’s ANDA Product, prior to the expiration of the ’229 patent constitutes infringement of one or more of the claims of the ’229 patent under 35 U.S.C. § 271(e)(2)(A).

Answer: Denied.

26. Upon information and belief, Ezra had actual and constructive knowledge of the ’229 patent prior to filing ANDA No. 20-7945 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the ’229 patent.

Answer: Ezra admits it was aware of the existence of the ’229 patent, but denies all remaining allegations.

27. Upon information and belief, Ezra intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Ezra’s ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 20-7945.

Answer: Ezra denies the allegations as such allegations relate to future events.

28. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Ezra’s ANDA Product would infringe one or more claims of the ’229 patent.

Answer: Denied.

29. Upon information and belief, use of Ezra’s ANDA Product in accordance with and as directed by Ezra’s proposed labeling for that product would infringe one or more claims of the ’229 patent.

Answer: Denied.

30. Upon information and belief, Ezra plans and intends to, and will, actively induce infringement of the ’229 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

Answer: Denied.

31. Upon information and belief, Ezra knows that Ezra’s ANDA Product is especially made or adapted for use in infringing the ’229 patent, and that Ezra’s ANDA Product is not suitable for substantial non-infringing use. Upon information and belief, Ezra plans and intends

to, and will, contribute to the infringement of the ’229 patent immediately and imminently upon approval of ANDA No. 20-7945.

Answer: Denied.

32. The foregoing acts by Ezra constitute and/or will constitute infringement of the ’229 patent, active inducement of infringement of the ’229 patent, and/or contribution to the infringement by others of the ’229 patent.

Answer: Denied.

33. Upon information and belief, Ezra acted without a reasonable basis for believing that it would not be liable for infringing the ’229 patent, active inducement of infringement of the ’229 patent, and/or contribution to the infringement by others of the ’229 patent.

Answer: Denied.

34. If Ezra’s infringement of the ’229 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

Answer: Denied.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

1. A judgment that one or more claims of the ’229 patent is not invalid, is enforceable and is infringed by Ezra’s submission of ANDA No. 20-7945, and that Ezra’s making, using, offering to sell, or selling in the United States, or importing into the United States of Ezra’s ANDA Product, will infringe the ’229 patent.

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 20-7945 shall be a date which is not earlier than the expiration date

of the ’229 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

3. An order permanently enjoining Ezra, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States Ezra’s ANDA Product, until after the expiration date of the ’229 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

4. Damages or other monetary relief to Plaintiffs if Ezra engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Ezra’s ANDA Product, prior to the expiration date of the ’229 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

5. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

Answer: Ezra denies Plaintiffs are entitled to any relief from the Court.

Ezra’s Affirmative Defenses

First Affirmative Defense:

Ezra’s proposed ANDA product will not infringe any claims of the ’229 patent.

Second Affirmative Defense:

The claims of the ’229 patent are invalid under one or more provisions of the patent laws, including but not limited to, 35 U.S.C. §§101, 102, 103, and/or 112.

Third Affirmative Defense:

One or more Plaintiffs are not entitled to any relief because they have not appropriately demonstrated or proven standing for the relief sought.

Fourth Affirmative Defense:

The patent term extension of the ’229 patent is invalid as violating 35 U.S.C. § 156(c)(4).

Fifth Affirmative Defense:

The ’229 patent is invalid for double-patenting as the extended term extends past another commonly-owned patent and the claims of the ‘229 patent would be obvious over the commonly-owned patent.

Sixth Affirmative Defense:

The ’229 patent is invalid for patent misuse for filing suit on patent claims the Plaintiffs know or should know to be invalid.

Seventh Affirmative Defense:

Ezra affirmatively pleads all defenses available pursuant to Rule 8(c) of the Federal Rules of Civil Procedure.

COUNTERCLAIMS FOR DECLARATORY JUDGMENT

For its counterclaims against Plaintiffs NOVARTIS AG (“Novartis”), NOVARTIS PHARMACEUTICALS CORPORATION (“NPC”), MISTUBISHI TANABE PHARMA CORPORATION (“MTPC”), AND MITSUI SUGAR CO., LTD. (“Mitsui”) (collectively, “Plaintiffs,” or “Counterclaim Defendants”), Defendant and Counterclaim-Plaintiff Ezra Ventures, LLC (“Ezra”) states as follows:

THE PARTIES

1. Ezra is a limited liability company organized and existing under the laws of the State of Arkansas, having its principal place of business at 401 S. Cedar Street, Little Rock, Arkansas, 72205.

2. Upon information and belief, Plaintiff Novartis AG is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

3. Upon information and belief, Plaintiff NPC is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in East Hanover, New Jersey.

4. Upon information and belief, Plaintiff MTPC is a corporation organized and existing under the laws of Japan, having an office and place of business at 2-6-18, Kitahama, Chuo-ku, Osaka 541-8505, Japan.

5. Upon information and belief, Plaintiff Mitsui is a corporation organized and existing under the laws of Japan, having an office and place of business at 36-2, Nihonbashi Hakozakicho, Chuo-ku 103-8423, Tokyo, Japan.

JURISDICTION AND VENUE

6. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and under the patent laws of the United States, Title 35 of the United States Code; and under 21 U.S.C. §355(j)(5)(C).

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1337, 1338(a), 2201, and 2202; and under 21 U.S.C. §355(j)(5)(C).

8. Plaintiffs are subject to personal jurisdiction in this Judicial District because Plaintiffs subjected themselves to the jurisdiction of this Court by filing their Complaint here.

Plaintiffs are also subject to personal jurisdiction in this District because they sell products here including the GILENYA® product that is the subject of this case, because they regularly conduct business here, and because they have purposely availed themselves of the benefits of jurisdiction in this State.

9. In view of this Court's May 11, 2015 Order (D.I. 27), this Court has determined that venue is proper in this Court, subject to Ezra's right to renew its motion to dismiss for lack of personal jurisdiction after the Federal Circuit Court of Appeals issues its decisions in the pending interlocutory appeals concerning personal jurisdiction over ANDA defendants.

BACKGROUND

10. The USPTO issued U.S. Patent No. 5,604,229 ("the '229 patent") on February 18, 1997.

11. In the Complaint, Plaintiffs assert that the '229 patent is owned by Mitsui and MTPC and exclusively licensed to Novartis.

12. Upon information and belief, NPC holds approved New Drug Application ("NDA") No. 22-527 for 0.5 mg fingolimod capsules, which are prescribed and sold in the United States under the name "GILENYA®."

13. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

14. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

15. An NDA may include, *inter alia*, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an authorized party. *See* 21 U.S.C. § 355(b)(1), -(c)(2); 21 C.F.R. § 314.53(b), -(c)(2).

16. On request from an NDA holder, the FDA automatically lists the NDA holder's disclosed patents pursuant to 21 U.S.C. §§ 355(b)(1) and (c)(2) in the publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "*Orange Book*." The FDA does not evaluate whether the claims of the disclosed patents actually cover the drug or method of using such drug, or whether the patent is valid; its actions are "purely ministerial." *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 243 (4th Cir. 2002).

17. Upon information and belief, NPC caused the '229 patent to be listed in the *Orange Book* in connection with NDA No. 22-527.

18. Ezra filed Abbreviated New Drug Application ("ANDA") No. 20-7945 seeking FDA approval to market its version of fingolimod capsules of 0.5 mg dosage strength ("Ezra's fingolimod product") and made reference to NDA No. 22-527. As part of Ezra's ANDA, Ezra submitted a paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), that the patent-in-suit is invalid, unenforceable, and/or not infringed by Ezra's fingolimod product.

19. On January 2, 2015, Ezra sent a letter to Plaintiffs notifying them that Ezra had submitted ANDA No. 20-7945 to the FDA and that the ANDA contained a paragraph IV certification that the '229 patent is invalid, unenforceable, and/or not infringed by its proposed generic product (the "January 2, 2015 notice letter").

20. Upon information and belief, none of Plaintiffs accepted Ezra's offer of confidential access to relevant portions of ANDA 20-7945, which would have enabled Plaintiffs, independently or collectively, to determine whether Ezra's fingolimod product would infringe any valid claim of the '229 patent, and ultimately conserve judicial resources.

21. Ezra's January 2, 2015 notice letter initiated a 45-day statutory period during which Plaintiffs had the opportunity to file an action for patent infringement.

22. On February 13, 2015, Plaintiffs sued Ezra alleging infringement of the '229 patent. There has been and is now an actual and justiciable controversy between Ezra and Plaintiffs as to whether the products described in ANDA No. 20-7945 infringe, induce infringement, or contribute to the infringement of any valid enforceable claim of the '229 patent.

COUNTERCLAIM COUNT 1: NON-INFRINGEMENT OF THE '229 PATENT

23. Ezra re-alleges and incorporates the allegations of paragraphs 1-22 as if fully set forth herein.

24. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid claim of the '229 patent will be infringed by the manufacture, use, sale, offer for sale, or importation into the United States of the fingolimod product described by ANDA No. 20-7945.

25. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, offering for sale, or importation of the fingolimod product described by ANDA 20-7945 will infringe any valid and enforceable claim of the '229 patent.

26. Ezra is entitled to a judicial declaration that the manufacture, use, sale, offering for sale, or importation of the fingolimod product described by ANDA 20-7945 will not infringe, directly or indirectly, any valid claim of the ’229 patent.

COUNTERCLAIM COUNT 2: INVALIDITY OF THE ’229 PATENT

27. Ezra re-alleges and incorporates the allegations of paragraphs 1-26 as if fully set forth herein.

28. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the ’229 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

29. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, offering for sale, or importation of the fingolimod product described by ANDA No. 20-7945 will infringe any valid and enforceable claim of the ’229 patent.

30. Ezra is entitled to a judicial declaration that the claims of the ’229 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created basis for invalidation and unenforceability.

COUNTERCLAIM COUNT 3:
INVALIDITY OF THE PATENT TERM EXTENSION

31. Ezra re-alleges and incorporates the allegations of paragraphs 1-30 as if fully set forth herein.

32. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the patent term extension of the ’229 patent is invalid as violating 35 U.S.C. § 156(c)(4).

33. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, offering for sale, or importation of the fingolimod product described by ANDA No. 20-7945 will infringe any valid and enforceable claim of the ’229 patent.

34. Ezra is entitled to a judicial declaration that the patent term extension of the ’229 patent is invalid as violating 35 U.S.C. § 156(c)(4).

EZRA’S PRAYER FOR RELIEF

WHEREFORE, Ezra respectfully requests that the Court enter a Judgment and Order in their favor and against Plaintiffs as follows:

A. For a declaration that the filing of Ezra’s ANDA No. 20-7945 has not infringed, and any future marketing or sale of the ANDA product will not infringe, any valid and enforceable claim of the ’229 patent;

B. For a declaration that the claims of the ’229 patent are invalid;

C. For a declaration that the patent term extension of the '229 patent is invalid as violating 35 U.S.C. § 156(c)(4);

D. For a declaration that this case is exceptional in favor of Ezra and awarding attorney’s fees pursuant to 35 U.S.C. § 285, other statutes or rules, or the general power of the Court;

E. For an award of costs and expenses; and

F. For such other relief as the Court determines to be just and proper.

Dated: May 27, 2015

STAMOULIS & WEINBLATT LLC

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CERTIFICATE OF SERVICE

I hereby certify that on May 27, 2015, I electronically filed the foregoing document with the Clerk of Court using the CM/ECF system which will send notification of such filing via electronic mail to all counsel of record.

/s/ Stamatios Stamoulis
Stamatios Stamoulis #4606